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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,282	11/19/2003	Scott R. Presnell	00-49C1	8902

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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	

Brian J. Walsh
Patent Department
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,282	PRESNELL ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/19/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status Claims:

1. Claims 1-14 are pending and under consideration.

Information Disclosure Statement:

2. The information disclosure statement (IDS) submitted 19 November 2003 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits. However, the Examiner states for the record that the relevancy of the instant Blast results is unclear.

Specification:

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested "nucleic acid encoding human cytokine receptor".

Claim Rejections - 35 U.S.C. § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-14 of the instant invention are directed to an isolated nucleic acid encoding a polypeptide that comprises of amino acid residues 36-753 and 1-753 of SEQ ID NO:2, a vector comprising said nucleic acid, a recobminant host cell comprising said vector and a method of producing the encoded protein.

The specification describes the claimed nucleic acid as encoding a novel receptor designated as "Zcytor18" (see page 2, lines 7-11). Instant specification states that the Zcytor18 gene is strongly expressed in testicular, ovarian and uterine tissue and moderately expressed in fetal heart, fetal bladder, fetal kidney, fetal skin and adult brain, (see page 3, lines 3-11). The specification also states that the level of Zcytor18 gene expression is higher in breast tissue than in normal breast tissue and that it can be used to differentiate tissues, (see page 3, lines 10-11). It is unclear if it is higher in breast cancer tissue as compared to normal breast tissue.

However, the instant specification does not disclose any information regarding physiologic or functional characteristics of the protein encoded by the claimed nucleic acid. Furthermore, the polypeptide encoded by the claimed nucleic acid has never been expressed, no biological activity was assayed or determined for it, its endogenous ligand is not identified and only a deduced amino acid sequence and general methods of expressing recombinant proteins is disclosed. For example the specification discloses that the polypeptide of the instant invention has a putative signal sequence at amino acid residues 1-35, while claim 14, recites that the signal sequence consists of amino acid resides 1-25 of SEQ IS NO:2. Therefore, it appears that Applicants are not aware of which residues of SEQ ID NO:2 represent the signal sequence.

The Instant specification asserts that the polypeptide encoded by the claimed nucleic acid can be used; to generate antibodies (page 37, lines 6-10), to identify and isolate Zcyor18 ligands, (page 50, lines 34-37), to differentiate tissues, to modulate the immune system by binding to Zcytor18 ligand, (see page 69, lines 29-35), and can be used therapeutically.

One asserted utility for the polypeptide encoded by the claimed nucleic acid is to raise antibodies, however, using a protein to generate antibodies does not afford said protein a specific utility since any protein can be used to generate antibodies. Another asserted utility is the therapeutic use of the claimed invention, however, while the instant specification asserts that the polypeptide encoded by the claimed nucleic acid can be used therapeutically, and discloses conventional protein and nucleic acid administration techniques, it does not disclose specific diseases which can be treated or diagnosed using the claimed nucleic acid or the encoded polypeptide. The specification establishes no connection between any physiological condition or disorder and the claimed invention, i.e, is the claimed nucleic acid or the encoded polypeptide over expressed, under expressed or completely lacking in any disorder? The specification provides no activity of the polypeptide encoded by the claimed nucleic acid, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein. Therefore, one of ordinary skill in the art would not be able to predict the activity or physiological importance of the polypeptide encoded by the claimed nucleic acid. Another asserted utility for the polypeptide encoded by the claimed nucleic acid is to identify and isolate Zcyor18 ligands, however, using the claimed nucleic acid to

produce the encoded protein for research purposes, does not afford the claimed nucleic acid specific, substantial and well established utility, because, a compound to be used as a scientific tool where what is being studied is the material itself, does not appear to be a specific, substantial or well established utility. Furthermore, the instant specification does not disclose any information regarding the biological activity or functional data of the protein encoded by the claimed nucleic acid, therefore, one of ordinary skill in the art would not know how to use it to modulate the immune system as applicants have asserted. Applicants submit an expression pattern for the Zctor18 gene, however, in order for a nucleic acid or the encoded polypeptide to be useful, in differentiating tissues, there must be a disclosed correlation or relationship between the claimed nucleic acid or the encoded polypeptide and a disease or disorder. The presence of the Zcytor18 gene in the stated tissues is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed Zcytor18 gene and a disease. The Instant specification discloses that the Zcytor18 gene is higher in breast tissue than in normal breast tissue and that it can be used to differentiate tissues, (see page 3, lines 10), however, it is unclear, whether this gene is higher in breast cancer tissue compared to normal tissue.

The claimed invention is directed to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance, therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant nucleic

acid and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

4b. Claims 1-14 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not define the physiological role of the Zcytor18 polypeptide encoded by the claimed nucleic acid, neither does it establish a link between this protein and a disease or a physiological condition. Therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The specification discloses only the sequence of the claimed nucleic acid and the encoded protein, and that is insufficient to establish a specific or substantial utility for the claimed invention.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 2 is drawn to an isolated nucleic acid, however, the claim recites "wherein the polypeptide comprises SEQ ID NO:2", which renders the claim indefinite because it appears the claim is drawn to a polypeptide. It is suggested that the claim be amended

to recite "wherein the encoded polypeptide comprises the amino acid sequence set forth in SEQ ID NO:2".

5b. Claim 3 is indefinite for reciting "wherein the polypeptide is SEQ ID NO:2", because is it unclear whether "is" is open language or closed language. It is suggested that the claim be amended to recite "comprises" which is open language, or "consists" which is closed language.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art unit 1647
16 February 2006

Eileen B. O'Hara

EILEEN B. O'HARA
PATENT EXAMINER